

K133030
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SECTION 6 - 510(k) Summary of Safety & Effectiveness DynaCAD/Prostate Interventional

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Contact Person (modified 2014-01-15):

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Date Prepared:

January 15, 2014

Proprietary Name/Classification Name:

Proprietary/Trade Name: DynaCAD/Prostate Interventional
Common Name: Image-guided, interventional planning software
Classification Name: Picture archiving and communications system
Class II: 21 CFR 892.2050
Product Code: LLZ

Predicate Device (to which equivalence is claimed) (modified 2014-01-15):

Proprietary/Trade Name: DynaCAD V1.0
Common Name: Magnetic Resonance Diagnostic device &
Picture Archiving and Communications System
Classification Name: System, Nuclear Magnetic Resonance Imaging
Class II: 21 CFR 892.1000, 21 CFR 892.2050
Product Code: LNH, LLZ
Premarket Notification : K041286

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DynaCAD/Prostate Interventional

Device Description:

DynaCAD/Prostate Interventional (a.k.a. DynaLOC/Prostate) is medical device software that is intended to be loaded onto a commercially available computer workstation. The DynaLOC/Prostate software application is designed for use with the DynaTRIM positioning device. The software receives DICOM images from a pre-procedure magnetic resonance (MR) study and performs calculations to assist the clinician with adjustments to the DynaTRIM positioning device. The software does not directly control the DynaTRIM device, the interventional accessories or the MR scanner. The users must manually adjust the DynaTRIM device and confirm proper positioning of the interventional accessories via an MR verification scan. Additionally, the users must manually control the MRI scanner to obtain the correct MR data sets.

Indications for Use (modified 2014-01-15):

DynaCAD/Prostate Interventional is a computer-based image-guidance accessory for use with commercially available Magnetic Resonance (MR) imaging systems and interventional devices.

The application provides the user with patient data processing, visualization and storage functions. It allows image analysis, display and recording of simulated images of a tracked insertion tool, such as a needle guide or sleeve, on a computer monitor or other display that shows images of the target organs and the current and/or projected path of the interventional instrument.

The device is intended to be used by physicians in a clinical setting for treatment planning and guidance for clinical, interventional and/or diagnostic procedures of the prostate.

Substantial Equivalence Discussion (modified 2014-01-15):

The DynaCAD/Prostate Interventional software (a.k.a. DynaLOC/Prostate) is used to facilitate clinical workflow for magnetic resonance image (MRI)-assisted interventional procedures of the prostate. The DynaLOC/Prostate software is used with the DynaTRIM positioning device and associated interventional accessories, which are supplied separately. The DynaLOC/Prostate software module is substantially equivalent to the DynaCAD V1.0 (K041286) system. The wording of the indications for use statement differs between the primary predicate and proposed device; however, the statements are equivalent with respect to use for MR-guided interventional planning with interventional hardware.

	Predicate Device:	Reference Predicate
510(k) Name	DynaCAD V1.0 (DynaLOC module)	PERCUNAV (preoperative planning module)
510(k) Number	K041286	K121498
FDA Clearance Date	July 21, 2004	December 14, 2012

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DynaCAD/Prostate Interventional

Device Similarities

The DynaLOC/Prostate 510(k) subject device and predicates have similar technologies for planning of interventional procedures. Both include software written to run on a Windows platform; both function as a kiosk, not allowing the end-user to access any operating system functions or system configuration panels; both have the ability to import magnetic resonance DICOM images from various sources, such as a computer network or removable media; both display fiducial-tracked instrumentation in relation to the patient anatomy; both require instrument registration and verification images prior to the actual intervention.

Device Differences

The software code base for the DynaLOC/Prostate software is equivalent to the DynaLOC module for primary predicate device, DynaCAD V1.0 (K041286). Both devices are used with interventional positioning devices; however, the type of hardware used differs because of the target anatomy and approach. The predicate is used with interventional devices that allow a percutaneous approach (e.g. breast biopsies). The proposed device is used with the DynaTRIM device for planning prostate interventions.

Reference Predicate (modified 2014-01-15):

The key difference between the 510(k) subject device and reference PERCUNAV predicate from an overall system perspective is that PERCUNAV predicate offers real-time navigation capabilities using ultrasound technology and fusion of images from multiple modalities (MR, CT, PET, SPECT etc.), whereas the DynaCAD system uses only one image modality, magnetic resonance (MR) imaging. Although the PERCUNAV system includes a pre-procedure planning module that is similar to the DynaLOC/Prostate module of the DynaCAD system, it is in a different regulation number (21 CFR 892.1750) than the 510(k) subject device. As such, it is considered a reference predicate for the purpose of the substantial equivalency discussion.

Another key difference is the PERCUNAV predicate does not include the DynaTRIM positioning device and accessories; however, PERCUNAV does include other interventional equipment, such as probes and needle assemblies. Although the PERCUNAV predicate offers more features than the 510(k) subject device, the pre-procedure planning module of the PERCUNAV predicate closely matches the features and workflow for the DynaCAD/Prostate Interventional system. The PERCUNAV pre-procedure planning software may be used with MR images alone (without ultrasound) and interventional devices in much the same manner as the DynaLOC/Prostate software module is used with the DynaTRIM device.

Indications for Use Differences (modified 2014-01-15):

The DynaCAD/Prostate Interventional indications statement is not identical to that of the DynaCAD V1.0 (K041286) predicate:

- The features that do not apply to the 510(k) subject device were removed;
- The limitation of percutaneous procedures was removed; and
- Reference to the prostate organ was added.

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DynaCAD/Prostate Interventional

These changes do not raise new issues of safety and effectiveness. Use of the DynaLOC/Prostate software with the DynaTRIM positioning device allows planning of standard prostate interventions (e.g. transrectal approach with biopsy guns).

Preclinical & Clinical Data

The safety and effectiveness of the DynaCAD/Interventional software (a.k.a. DynaLOC/Prostate) for the proposed indications for use is supported by preclinical software verification and validation testing. This includes validation of the software with the DynaTRIM device in a simulated clinical use setting.

Conclusion (modified 2014-01-15):

The DynaLOC/Prostate software application is similar to the DynaLOC software for the predicate DynaCAD V1.0 (K041286) system. The wording of the indications for use statement differs between the primary predicate and proposed device; however, the statements are equivalent with respect to use for MR-guided interventional planning with interventional hardware. Since the proposed device is used with the DynaTRIM positioning device, reference to the prostate organ was added to the indications statement. Also, the predicate clearance includes statements related to the other modules of the DynaCAD software applications. Since these do not pertain to the DynaLOC/Prostate module, they were not included in the proposed indications for use statement.

Since the DynaCAD V1.0 (K041286) clearance is limited to percutaneous procedures (e.g. breast), the pre-procedure planning module of the PERCUNAV system (K121498) was selected as a reference predicate. The characteristics and workflow for the DynaLOC/Prostate software is similar to those of the preoperative planning module of the PERCUNAV predicate (K121498), which is not limited to percutaneous procedures.

The results of software verification and validation testing support that the DynaLOC/Prostate software is safe and effective when used with the DynaTRIM device for prostate interventional procedures. Therefore, the DynaCAD/Prostate Interventional planning software (DynaLOC/Prostate) is substantially equivalent to the predicate DynaLOC software application cleared in K041286 (DynaCAD V1.0).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 22, 2014

Invivo Corporation
Attn: Mr. Michael Preto
Regulatory Affairs Specialist
3545 S W 47th Avenue
GAINSVILLE FL 32608

Re: K133030

Trade/Device Name: DynaCAD/Prostate Interventional (aka DynaLOC/Prostate)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 12, 2013
Received: December 13, 2013

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Michael D. O'Hara For

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

SECTION 5 - Indications for Use
DynaCAD/Prostate Interventional
(revised 102113)

510(k) Number (if known): **k133030**

Device Name: DynaCAD/Prostate Interventional

Indications for Use:

DynaCAD/Prostate Interventional is a computer-based image-guidance accessory for use with commercially available Magnetic Resonance (MR) imaging systems and interventional devices.

The application provides the user with patient data processing, visualization and storage functions. It allows image analysis, display and recording of simulated images of a tracked insertion tool, such as a needle guide or sleeve, on a computer monitor or other display that shows images of the target organs and the current and/or projected path of the interventional instrument.

The device is intended to be used by physicians in a clinical setting for treatment planning and guidance for clinical, interventional and/or diagnostic procedures of the prostate.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k):